

**Remarks**

**Introduction**

Applicant respectfully requests reconsideration of the currently pending claims based on the arguments presented below.

**Priority**

The Examiner maintains that claims 21-35 and 41 are not entitled to the priority date of parent application 08/680,845, filed December 5, 1997, now issued as U.S. Patent No. 6,080,728 (“the Parent Application”). Specifically, the Examiner states that (1) the claims recite the term “nucleotide,” (2) that the term nucleotide includes RNAs and (3) there is no support for RNA embodiments in the Parent Application.

Applicant agrees with the Examiner’s interpretation of the term “nucleotide” as encompassing RNA. The term “nucleotide” is a common and well understood term in the biological sciences and is known to include both DNA and RNA. The term “nucleotide” also contains a well defined chemical structure comprising a base, a sugar and a phosphate. See Lewin, *Genes V* (1993) page 87.

The Examiner maintains that because there is no support for RNA embodiments, that the term “nucleotide” which includes RNA embodiments is not supported (*i.e.*, that there is not adequate written description) by the Parent Application. The Examiner also maintains that the term “nucleotide” is used in the specification to describe a DNA nucleotide not an RNA molecule. Applicant respectfully traverses this holding by the Examiner.

Applicant submits that, as a matter of law, written description is presumed to be adequate until sufficient evidence to the contrary has been presented by the Examiner to rebut this presumption. The Examiner must have a reasonable basis to challenge the adequacy of the written description and the Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims. *See MPEP 2163.04 (Rev. 2, May 2004, page 2100-179, citing In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1970)).*

The Examiner maintains that the written description is not adequate in the Priority Application, because the Priority Application does not provide support for RNA embodiments. Applicant respectfully submits that the Examiner's reasoning is that the generic term "nucleotide" which includes both DNA and RNA is not supported because the Parent Application does not provide examples of RNAs. Applicant respectfully submits that the Examiner has not provided evidence or reasoning for why a lack of RNA examples means that the generic term "nucleotide" lacks adequate written description.

The written description inquiry is a cases-by-case determination and is a question of fact. See MPEP 2163.04 (Rev. 2, May 2004, page 2100-179, citing *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976)). The written description requirement is satisfied when the application shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention. See MPEP 2163 (Rev. 2, May 2004, page 2100-165, citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)). The Parent Application provides clear literal (*i.e., ipsis verbis*) support for the claimed term "nucleotide" and therefore one skilled in the art would at the time of filing immediately recognize that the inventors were in possession of an invention using nucleotides. The Examiner has not disputed that the term "nucleotide" finds literal support in the Parent Application. The term "nucleotide" has a well known meaning in the art and also has a well defined chemical structure, as is discussed above. The Examiner has not disputed that the term "nucleotide" has a well known chemical structure. It appears, applicant respectfully submits, that the sole basis for the Examiner's rejection is that claimed recitation of a "nucleotide" genus is not adequately supported because the Parent Application fails to contain RNA examples.

Applicant respectfully submits that adequate written description of a claimed genus does not require an explicit description of each species falling within the genus. Adequate written description of a genus requires only that the specification disclose a “representative number of species” falling within the claimed genus. A representative number of species is satisfied by the disclosure of relevant and identifying characteristics, such as, structure or other physical and/or chemical characteristics. *See MPEP 2163 (Rev. 2, May 2004, page 2100-174).* As discussed above, the Examiner has not disputed that the term “nucleotide” has a well known and well defined chemical structure.

Moreover, the Parent Application provides numerous examples of DNA nucleotide embodiments, which applicant submits provides further evidence for why the term “nucleotide” is supported by the Parent Application. Applicant submits that a genus may be adequately described by only a single species. *See MPEP 2163 (Rev. 2, May 2004, page 2100-174).* Moreover, a description of a limited number of species will provide adequate support for a claimed genus unless there is an unpredictability in the art such that the specifically enumerated species do not predict the operability of other species falling within the genus. *See MPEP 2163 (Rev. 2, May 2004, page 2100-174, citing In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)).*

The Examiner has provided no evidence for why one skilled in the art would fail to recognize that that RNA nucleotides would be operable for the claimed invention based on the explicit description of DNA nucleotide species in the Parent Application. In fact, the Examiner has made a factual determination to the contrary.

Namely, the Examiner has made a determination that RNA nucleotides and DNA nucleotides are art recognized equivalents for the claimed invention. *See Office Action at page 9.* Given the Examiner’s determination that RNA and DNA are art recognized equivalents for the claimed invention, applicant respectfully submits that the disclosure in the Parent Application of numerous DNA nucleotide embodiments provides adequate written description for a claim to “nucleotides,” which includes both DNA and RNA.

Finally, the Examiner argues on page 4 of the Office Action that the term “nucleotide” is used in the specification to refer to DNA nucleotides. Even if one accepts, solely for the sake of argument, that the term “nucleotide” is used in the specification to refer to DNA nucleotide embodiments, it is undisputed that the term “nucleotide” has an ordinary and customary meaning in the art, which meaning includes both DNA and RNA.

Terms in a patent application are presumed to have the ordinary and customary meaning attributed to them by those of ordinary skill in the art. *See MPEP 2111.01 (Rev. 2, May 2004, page 2100-48, citing Sunrace Roots Enter. Co v. SRAM Corp., 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003)).* Applicant respectfully submits that this is clearly not an instance where the applicant has acted as his own lexicographer and has defined the term nucleotide contrary to its well recognized meaning in the art. *See MPEP 2111.01 (Rev. 2, May 2004, page 2100-50).* Moreover, the Examiner has found that DNA and RNA are art recognized equivalents in the context of the claimed invention. Absent, an applicant acting as his own lexicographer, the established art recognized meaning of a term must be applied.

In view of the foregoing, applicant respectfully requests reconsideration and withdrawal of the Examiner’s finding that the claims lack adequate support in the Parent Application.

### **Double Patenting**

Applicant respectfully requests that this rejection be held in abeyance until the claims are found otherwise allowable.

### **Claim Rejections Under 35 U.S.C. § 112, first paragraph**

The Examiner has rejected claims 21-35 and 41 as new matter, *i.e.*, as lacking adequate written description in the specification. The Examiner maintains that while the specification supports nucleotides encoding anti-angiogenic proteins or peptides, that the specification provides no support for the broader genus of nucleotide sequences that inhibit tumor angiogenesis. The Examiner states that the presently claimed genus would include antisense and ribozyme molecules that inhibit the expression of angiogenesis protein and peptides as well as nucleic acids that encode transcriptional repressors of angiogenic genes. The Examiner further states that the specification fails to describe a single example of such a nucleotide.

Applicant respectfully incorporates the written description legal standards set forth above in the priority section in response to this rejection. Applicant further submits that there is literal description for each of the claim elements of the claimed genus in the specification. The Examiner has not disputed this. The Examiner's position appears to be the same position taken in the priority section above, namely that the claimed genus lacks adequate written description because it fails to provide examples of certain embodiments falling within the claimed genus.

Applicant respectfully submits that the burden is on the Examiner to show that the claims lack adequate written description and, assuming for the sake of argument, that the specification does not provide explicit mention of the embodiments listed by the Examiner above, this does not, by itself, mean that the claims lack written description. As stated above, the specification need only describe a representative number of species.

Moreover, when one of skill in the art would recognize that the enumerated species in the specification would be clearly operable for other species included in a genus claim, then the mention of even a single species provides adequate written description. Applicant respectfully submits that the numerous embodiments of DNA nucleotides set forth the specification and in the Parent Application provide adequate support for the claimed genus, given the level of skill in the art and given the Examiner's finding that RNA and DNA are art recognized equivalents in the context of the present invention.

In particular, applicant respectfully submits that it would necessarily be understood by the skilled artisan that, for example, the use of RNA as a nucleotide according to the specification would be accompanied by the use of RNA, for example, that would correspond to an angiogenic protein or peptide. Thus, even if the specification does not provide explicit support for the use of RNA antisense, ribozymes or transcriptional repressors, (1) support for these species is inherent in the specification and (2) because an representative number of DNA species are provided in the specification to support the claimed genus, an explicit description for these species is not required for there to be adequate written description.

In view of the foregoing, applicant respectfully requests reconsideration and withdrawal of the present rejection.

### **Obviousness Rejections**

The Examiner has rejected the claims as obvious over the prior art. A necessary assumption of this rejection is that the claims are not adequately supported by the Parent Application. In view of applicant's traversal of this matter above, applicant respectfully requests that the obviousness rejection be reconsidered and withdrawn by the Examiner.

## CONCLUSION

In view of the foregoing, applicant respectfully requests reconsideration and withdrawal of the pending rejections and notification of allowance of the pending claims, subject to resolution of the double patenting rejection.

Respectfully submitted,

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